

September 3, 2003

to:

Phillip Gambel

(703) 746- 5293

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Paralegal Specialist

From the desk of ...

Dianne E. Maggard Paralegal Speciatist Board of Patent Appeals & Interferences 1225 Jefferson Davis Highway, Crystai Gateway 2, 12A06A Adlagton, VA 22202

(703) 305-4673 Fax: (703) 308-6200

The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

Paper No. 38

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CAMPBELL ROGERS, ELAZER R. EDELMAN, and DANIEL I. SIMON

MAILED

Application No. 08/823,999

APR 2 3 2003

PAT. & T.M. OFFICE VARD OF PATENT APPFORD INTERFERENCE

HEARD: April 1, 2003

Before WINTERS, GRIMES, and GREEN, <u>Administrative Patent Judges</u>.
WINTERS, <u>Administrative Patent Judge</u>.

VACATUR OF REJECTIONS AND REMAND TO THE EXAMINER

On consideration of the record, we find that this case is not ready for a disposition on appeal. Under the circumstances, we <u>vacate</u> each of the examiner's rejections and <u>remand</u> this application for evaluation of patentability not inconsistent with the views expressed herein.

First, before entering rejections under 35 U.S.C. §§ 112, 102, or 103, it is important to ascertain the full scope of applicants' claimed subject matter. See Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1567-68, 1 USPQ2d 1593, 1597 (Fed.

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Cir.), cert. denied, 481 U.S. 1052 (1987) ("Claim interpretation, in light of the specification, claim language, other claims, and prosecution history, is a matter of law and will normally control the remainder of the decisional process en route to a conclusion under 35 U.S.C. § 103"); In re Geerdes, 491 F.2d 1260, 1262, 180 USPQ 789, 791 (CCPA 1974) (Before considering rejections under 35 U.S.C. §§ 103 and 112, court must first decide whether claims include within their scope the presence of recognized blowing agents); In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971)(Claims must be analyzed first to determine exactly what subject matter they encompass before considering whether scope of protection sought is supported and justified by specification disclosure under 35 U.S.C. § 112, first paragraph). As stated in In re Hiniker Co., 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998)(citing Giles Sutherland Rich, Extent of Protection and Interpretation of Claims—American Perspectives, 21 Int'l Rev. Indus. Prop. & Copyright L. 497, 499 (1990)), "the name of the game is the claim."

With those principles in mind, we here reproduce independent claim 1 which is illustrative of the subject matter on appeal:

1. A method of inhibiting or reducing <u>stenosis</u> or <u>restenosis</u> of a blood vessel following injury to vascular tissue in a region of the blood vessel of a patient in need of treatment thereof, comprising:

administering systemically or at the site of the injury a pharmaceutically acceptable composition comprising a compound which specifically inhibits or reduces leukocyte integrin - mediated adhesion or function, wherein the integrin is selected from the group consisting of Mac-1(CD11b/CD18), LFA-1 (CD11a/CD18),p 150,95 (CD11c/CD18), and CD11d/CD18, wherein the compound is selected from the group consisting of antibodies and antibody fragments that are immunoreactive with the integrins or their ligands and which block the interaction of the integrins or their ligands

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with vascular cells; molecules which inhibit expression of the integrins or their ligands, and peptides and peptidomimetics derived from the integrins or their ligands which block the interaction of the integrins or their ligands with vascular cells or tissues, in an amount effective to inhibit or reduce <u>stenosis or dependent restenosis</u> of a blood vessel following injury to vascular tissue. [emphasis added]

On return of this application to the examining corps, we recommend that applicants and the examiner clarify just what is covered by the terms "stenosis," "restenosis," and "dependent restenosis" in claim 1. This is essential, we believe, in resolving any issues which may arise under 35 U.S.C. §§ 112, 102, or 103. In this regard, we make of record Taber's Cyclopedic Medical Dictionary, 18th ed., pp. 130, 1666, and 1828 (1997). Taber's sets forth a definition of stenosis ("The constriction or narrowing of a passage or orifice"); aortic stenosis ("Narrowing of the aorta or its orifice due to lesions of the wall with scar formation"); and restenosis ("The recurrence of a stenotic condition as in a heart valve or vessel"). On return of this application, we suggest that applicants state for the record whether their usage of "stenosis" and "restenosis" in claim 1 is identical to Taber's. We also suggest that applicants clarify whether there is any difference in scope between "restenosis" and "dependent restenosis," as those terms are used in claim 1. Again, according to Taber's, aortic stenosis constitutes a narrowing of the aorta or its orifice due to lesions of the wall with scar formation; and this is but one form of stenosis, the constriction or narrowing of a passage or orifice.

Second, in responding to applicants' arguments on appeal, the examiner invites attention to Genetta at page 14 of the Examiner's Answer (Paper No. 29). The

¹ Genetta et al. (Genetta), "ABCIXIMAB: A New Antiaggregant Used in Angioplasty," <u>Annals of Pharmacotherapy</u>, Vol. 30, pp. 251-257 (March 1996)

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examiner does not, however, include Genetta in the statement of a prior art rejection under 35 U.S.C. § 102 or 35 U.S.C. § 103. This is inexplicable because Genetta appears to constitute more relevant prior art than the references which, to date, have been applied against applicants' claims. For example, Genetta discloses the following: "Clinical trials have indicated that abciximab can reduce the incidence of abrupt closure and <u>restenosis</u> associated with percutaneous transluminal coronary angioplasty (PTCA) performed in high-risk patients" (page 251, column 1, fourth paragraph, emphasis added). Again, according to Genetta, "[t]he data from this trial suggest that abciximab reduces the incidence of abrupt closure and <u>restenosis</u> following coronary intervention in high-risk patients" (page 254, column 1, third full paragraph, emphasis added). Genetta further discloses a pharmaceutical composition containing abciximab, suitable for injection (page 252, column 2, first full paragraph).

In considering this state of affairs, we believe that it would be imprudent, and not a sound use of the Board's resources, to adjudicate rejections presented by the examiner when Genetta appears to constitute the closest prior art. On return of this application, we recommend that the examiner reevaluate the patentability of applicants' claims in light of Genetta. If the examiner believes that any claim or claims are unpatentable over Genetta, he should issue an appropriate office action explaining his position and giving applicants full and fair opportunity to respond.

Third, based on our review of the file wrapper, it appears that applicants have submitted a number of abstracts of journal articles in an effort to rebut the examiner's findings and conclusions. Merely by way of example, we refer to Exhibits 4 and 5

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attached to the Appeal Brief. Exhibit 4 is an abstract of an article by Topol et al. appearing in JAMA, August 13, 1997 - Vol. 278, no. 6, pp. 479-84. Exhibit 5 is an abstract of article by Mickelson et al. appearing in JACC, Vol. 33, no. 1, January 1999, pp. 97-106. It also appears, with respect to some or all of those abstracts, that the examiner has retrieved a full text copy of the corresponding article. The examiner has not, however, completed a "Notice of References Cited" (PTO-892) or otherwise made of record the full text copies.

We are thus confronted with a situation where applicants and the examiner are "not on the same page." This became clear at oral hearing when the examiner referred to several passages in the full text of a journal article, and applicants' counsel expressed surprise because the article in its entirety is not of record.²

On return of this application to the examining corps, we recommend that the record be clarified. More specifically, whenever the full text of a journal article is available, we recommend that applicants rely on, and make of record, the full text rather than a mere abstract. Manifestly, the article in its entirety provides a more comprehensive picture of the prior art than its abstract. Likewise, in those instances where the examiner has retrieved the full text copy of a journal article, we recommend that the examiner complete a "Notice of References Cited" (PTO-892) or otherwise make of record the full text copy. This will serve to clarify the record; will reflect a more

² Patrea L. Pabst, Registration No. 31,284, represented applicants at the oral hearing on April 1, 2003. She was accompanied by one of the inventors, Dr. Daniel I. Simon. Phillip Gambel, Primary Examiner in Technology Center 1600, also presented an oral argument. See 37 CFR § 1.194(b).

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comprehensive picture of the prior art; and will place applicants and the examiner "on the same page."

Fourth, in rejecting applicants' claims for obviousness, the examiner states that

Claims 1-6, 8, 10-12 stand rejected under 35 U.S.C. § 103 as being unpatentable over Ricevuti et al. (Atherosclerosis 91: 1-14, 1991)

AND/OR Albelda et al. (FASEB J. 8: 504-512, 1994) AND/OR Coller et al. (U.S. Patent No. 5,770,198) AND/OR Simon et al. (Circulation 92, 8 Suppl: 1-110, Abstract 0519, 1995) in view of art known use of administering pharmaceutical reagents in various composition forms and at various intervention times and in further evidence of Neumann et al. (JACC 27: 819-824, 1996). [Paper No. 29, page 7, fourth paragraph]

That statement of rejection under 35 U.S.C. § 103 is not entirely clear. In view of the examiner's usage of the expression "AND/OR," it is unclear just how the references are combined; or how many permutations and combinations of references are relied on.

On return of this application to the examining corps, we recommend that the examiner reevaluate the patentability of claims 1 through 6, 8, and 10 through 12 under 35 U.S.C. § 103. If the examiner adheres to the position that applicants' claims are unpatentable on this ground, we recommend that the examiner (1) format the rejection in a more traditional manner; and (2) provide applicants with a full and fair opportunity to respond. See MPEP § 706.02(i).

As a related matter, we note the examiner's reliance on the "art known use of administering pharmaceutical reagents in various composition forms and at various intervention times" (Paper No. 29, page 7, fourth paragraph). Again, it is unclear just what this means. It is unclear whether the examiner would take official notice of specific facts and, if so, what those facts are and how they bear relationship to the

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claims. On return of this application, if the examiner adheres to the position that applicants' claims are unpatentable under 35 U.S.C. § 103 and takes official notice of facts outside the record, we recommend that the examiner follow the guidelines set forth in MPEP § 2144.03.

Fifth, in rejecting applicants' claims for lack of a novelty, the examiner states that "no more of the reference is required than that it sets forth the substance of the invention" (Paper No. 29, page 7, first and third paragraphs). The examiner does not, however, cite authority in support of that proposition and we are not aware of any.

Rather, as stated in Celeritas Tech. Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998), "It is well settled that a claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." On return of this application, if the examiner adheres to the position that applicants' claims are anticipated within the meaning of 35 U.S.C. § 102, we recommend that the examiner explain how each and every claim limitation is found either expressly or inherently in a single prior art reference.

Conclusion

In conclusion, we <u>vacate</u> each of the examiner's rejections and <u>remand</u> this application for further action not inconsistent with the views expressed herein. We emphasize that the term "vacate," as applied to an action taken by an appellate tribunal, means to set aside or to void. When the Board vacates an examiner's

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rejection, the rejection is set aside and no longer exists. Ex parte Zambrano,

58 USPQ2d 1312 (Bd. Pat. App. & Int. 2001).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

VACATED & REMANDED

Sherman D. Winters

Administrative Patent Judge

Eric Grimes

Administrative Patent Judge

Lora M. Green

Administrative Patent Judge

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Patrea L. Pabst Arnall, Golden, & Gregory, LLP 2800 One Atlantic Center 1201 West Peachtree Street Atlanta, GA 30309-3450

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